IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kroswek et al. Confirmation No.: 6569

Application No.: 10/669,277 Group Art Unit: 3627

Filed: September 23, 2003 Examiner: Haider, Fawaad

For: Systems and Methods For Supply Attorney Docket No.: 687197615001

CHAIN MANAGEMENT

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance, mailed January 11, 2010, from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/669,277 (hereinafter "the '277 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. 154(b) stating that the projected patent term adjustment to date is 1291 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) ("Determination") mailed January 11, 2010. Specifically, Applicants believe that the patent term adjustment of 1291 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, should be, at a minimum, equal to the period starting November 23, 2004 and ending September 23, 2006 (669 days) plus the period starting September 23, 2006 and ending the day that a patent issues on the above-identified application (estimated to be 1396 days), minus the period beginning on January 27, 2009 and ending on February 26, 2009 (30 days).

For the purpose of this Request, Applicants assume that the patent will issue on the above-identified application on July 20, 2010, which is the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the Determination. This date is the same projected issue date used by the PTO in the Determination. Applicants believe that the patent term adjustment should be, at a minimum, a total of 2035 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
 - (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following statement of facts:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **§200.00**.

Please charge the required fee to Jones Day Deposit Account No. 50-2724 (referencing 687197615001).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:
 - 1. <u>Correct patent term adjustment:</u>

The correct patent term adjustment is 2035 days, assuming that the patent on the above-identified application issues on July 20, 2010, which is the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the Determination (the same projected issue date used by the PTO in the Determination), which number of days is attributable to the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '277 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)) and the failure of the PTO to respond to a reply under 35 U.S.C. § 132 within four months after the date of the reply (delay under 37 C.F.R. § 1.702(a)(2)) (the "A period") minus the number of actual calendar days occurring in both the A period and in the "B period" described below; and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '277 application (delay under 37 C.F.R. § 1.702(b)) and minus the time during this period consumed by Applicant delay (see 35 U.S.C. § 154(b)(2)(C)(ii) and 37 C.F.R. § 1.704(b)).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) <u>Delay under 37 C.F.R. § 1.702(a) (the "A period")</u>

The delay by the PTO under 37 C.F.R. § 1.702(a) is 1321 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '277 application. *See* PTO's Patent Application Information Retrieval page for U.S. Application No. 10/669,277 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A). The '277 application was filed under 35 U.S.C. § 111(a) on September 23, 2003. The first notification under 35 U.S.C. § 132 (an Office Action) was mailed by the PTO on June 11, 2008. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application

was filed (*i.e.*, by Tuesday, November 23, 2004), and thus, the delay under 37 C.F.R. § 1.702(a)(1) includes 1296 days.

In addition, and also as acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to respond to respond to Applicant's Response of February 26, 2009 until July 21, 2009. Accordingly, the PTO did not respond to a reply under 35 U.S.C. § 132 not later than June 26, 2009, or four months after the date on which the reply was filed, and thus, the delay under 37 C.F.R. § 1702(a)(2) includes 25 days.

In sum, the number of days of delay in the A period, that is, under subsection (a)(1) of 37 C.F.R. § 1.702 is 1321 days.

(b) *Delay under 37 C.F.R.* § 1.702(b) (the "B period")

The delay by the PTO under 37 C.F.R. § 1.702(b) is <u>1396</u> days, assuming that the patent on the above-identified application issues on July 20, 2010, which is the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the Determination (the same projected issue date used by the PTO in the Determination).

The '277 application was filed under 35 U.S.C. § 111(a) on September 23, 2003. A patent has not yet issued; however, an Issue Fee payment authorization accompanies this Request. Accordingly, the PTO has not issued a patent within three years of the date on which the application was filed (in this case, September 23, 2006), and thus, the term of the patent should be adjusted because issuance has been delayed by 1396 days. Assuming that the patent on the above-identified application issues on Tuesday, July 20, 2010, Applicants submit that the period of delay by the PTO in the B period will be 1396 days. See 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (see "PTO PAIR Adjustment," Exhibit A).

(c) Overlapping Days in the Delay Periods

According to 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." *See* 35 U.S.C. § 154(b)(2)(A).

Applicants submit that the overlap of the actual calendar days of the A period, discussed in detail below, with the actual calendar days of the B period includes only the date ranges from September 23, 2006 until June 11, 2008 and from June 26, 2009 until July 21, 2009. These

ranges total 627 plus 25, or 652 days. Thus, the period of patent term adjustment on a patent that issues on the above-identified patent application is calculated as the sum of 1321 plus 1396 minus 652, which is equal to 2065 days.

Applicants respectfully submit that under controlling case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Kappos*, No. 2009-1120 (Fed. Cir. January 7, 2010) (hereinafter *Wyeth*), a copy of which is included here as Exhibit B.

In *Wyeth*, the Court held that "If an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(b)(2)."

Turning to the '277 application, the period of delay under subsection (a)(1) of 37 C.F.R. § 1.702 includes the days of November 23, 2004 to June 11, 2008 (1321 days). The period of delay under (a)(2) of 37 C.F.R. § 1.702 includes the days of June 26, 2009 to July 21, 2009 (25 days). The delay under 37 C.F.R. § 1.702(b) comprises September 23, 2006 to the day the patent on the '277 application issues, which is assumed to be July 20, 2010 (the date used by the PTO in the Determination).

Thus, the delay under 37 C.F.R. § 1.702(a)(1) occurring from November 23, 2004 to June 11, 2008 overlaps with the delay under 37 C.F.R. § 1.702(b) (September 23, 2006 to the day the patent on the '277 application issues) only for the dates September 23, 2006 to June 11, 2008. The delay under 37 C.F.R. § 1.702(a)(2) occurring from June 26, 2009 until July 21, 2009 overlaps completely with the delay under 37 C.F.R. § 1.702(b) (September 23, 2006 to the day the patent on the '277 application issues).

Consequently, under 35 U.S.C. § 154(b)(2)(A), the dates of delay from November 23, 2004 to September 23, 2006 under 37 C.F.R. § 1.702(a) do <u>not</u> overlap with the dates of delay under 37 C.F.R. § 1.702(b) from September 23, 2006 to July 20, 2010 (the assumed issue date used by the PTO in the Determination). Therefore, the total delay should be a summation of the delays under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) minus the sum of overlap and the sum of delay Attributable to Applicants, or <u>2035</u> days (the sum of 1321 plus 1396 days minus 652 days and minus 30 days), assuming that the patent on the '277 application issues on July 20, 2010, which is the Tuesday before the date that is 28 weeks (six and a half months) after the

mailing date of the Determination (the same projected issue date used by the PTO in the Determination.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:
 - 1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is "[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first." In particular, Applicants seek to include the delay under 37 C.F.R. § 1.702(a)(1) occurring from November 23, 2004 to September 23, 2006 (669 days) that occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b).

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that "the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued."

Applicants submit that this period consists of <u>1396</u> days for the period beginning the day after September 23, 2006 (the date that is three years after the date on which the '277 application was filed) and ending on the day that a patent issues on the '277 application, assuming that the patent on the '277 application issues on Tuesday, July 20, 2010, which is the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the Determination (the issue date assumed by the PTO in the Determination).

Applicants further submit that the 669 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap with any of the 1396 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants' believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total **2065** days, not 1321 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a) and (b) amounts to 2065 days. As discussed *supra* in section 2(i)(2)(b) and in section (iv) below, Applicants believe that there was a period of 30 days constituting a delay attributable to Applicants under 37 C.F.R. § 1.704(b). Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 2035 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 669 days plus 1396 days), less the sum of the period calculated under Section 1.704(b) (*i.e.*, 30 days).

- (iii) The '277 application is not subject to a terminal disclaimer.
- (iv) Applicants agree with the PTO that the '277 application is subject to 30 days of Applicant delay pursuant to 37 C.F.R. § 1.704(b), representing 30 days beyond three months after the mailing date of an Office action (in this case October 27, 2008), taken to reply (a reply was made on February 26, 2009).

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 2065 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 30 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 2035 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 2035 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that "[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*" (emphasis added). An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Conclusion

Applicants respectfully request that the above remarks be entered in the present application file. No fee other than the \$200 fee pursuant to 37 C.F.R. § 1.705(b)(1) estimated to

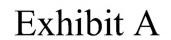
be due in connection with this Response. In the event that any additional fee(s) is required, please charge the required fee(s) to Jones Day Deposit Account No. 50-2724.

Respectfully submitted,

(404) 581-8052

Date: January 15, 2010 /Richard U. Campbell/

By: Richard U. Campbell (Reg. No. 57,914) **JONES DAY** 1420 Peachtree Street, N.E. Suite 800 Atlanta, Georgia 30309



10/669,277	SYSTEMS AND	METHODS FOR SU	IPPLY CHAIN MANAGEMENT	01-15	-2010::10:55:00
Patent Term	Adjustments				
Patent Term Ad	djustment (PTA) for	Application Number	: 10/669,277		
Filing or 371(c) Date:		09-23-2003	USPTO Delay (PTO) Delay (days):	1321
Issue Date of Patent:		-	Three Years:		-
Pre-Issue Petitions (days):		+0	Applicant Delay (APPL) Dela	y (days):	30
Post-Issue Petitions (days):		+0	Total PTA (days):		1291
USPTO Adjustm	nent(days):	+0	Explanation Of Calculations		
Patent Term	Adjustment Hi	story			
Date	Contents Desc	ription		PTO(Days)	APPL(Days)
01-11-2010	Mail Notice of Al	lowance			
12-31-2009	Document Verifi	cation			
12-31-2009	Notice of Allowa	nce Data Verificatior	n Completed		
10-06-2009	Workflow - Requ	iest for RCE - Begin			
10-15-2009	Date Forwarded	to Examiner			
10-15-2009	Date Forwarded	to Examiner			
10-06-2009	Request for Con	Request for Continued Examination (RCE)			
10-15-2009	Disposal for a RCE / CPA / R129				
10-01-2009	Mail Advisory Ac	tion (PTOL - 303)			
09-30-2009	Advisory Action	(PTOL-303)			
09-18-2009	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received				
09-18-2009	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received				
09-27-2009	Date Forwarded	to Examiner			
09-18-2009	Amendment afte	er Final Rejection			
07-21-2009	Mail Final Reject	ion (PTOL - 326)		25	
07-20-2009	Final Rejection			*	
05-14-2009	Date Forwarded	to Examiner		*	
02-26-2009	Response after I	Non-Final Action			30
10-27-2008	Mail Non-Final R	ejection			*
10-27-2008	Non-Final Reject	ion			
08-25-2008	Change in Powe	r of Attorney (May I	nclude Associate POA)		
08-19-2008	Correspondence	Address Change			
08-19-2008	Date Forwarded	to Examiner			
07-11-2008	Response to Ele	ction / Restriction Fil	ed		
07-11-2008	Request for Exte	ension of Time - Gra	nted		
06-11-2008	Mail Restriction	Requirement		1296	
06-09-2008	Requirement for	Restriction / Election	n	*	
10-17-2007	Withdraw Flagge	ed for 5/25		*	
10-16-2007	Flagged for 5/25			#	
10-03-2006	Case Docketed t	o Examiner in GAU		*	
02-28-2006	Case Docketed t	o Examiner in GAU		*	
06-03-2004	IFW TSS Process	sing by Tech Center	Complete	*	
06-03-2004	Case Docketed t	o Examiner in GAU		*	
04-15-2004	Preliminary Ame	endment		*	

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04-22-2004	Application Return from OIPE	11/2
04-22-2004	Application Return TO OIPE	*
04-22-2004	Application Dispatched from OIPE	**
04-22-2004	Application Is Now Complete	*
04-15-2004	Additional Application Filing Fees	*
04-15-2004	Workflow incoming amendment IFW	*
04-09-2004	Notice of Omitted Items	*
12-04-2003	Cleared by OIPE CSR	#
11-03-2003	IFW Scan & PACR Auto Security Review	4
09-23-2003	Initial Exam Team nn	*

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United States Court of Appeals for the Federal Circuit

2009-1120

WYETH and ELAN PHARMA INTERNATIONAL LIMITED.

Plaintiffs-Appellees,

٧.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY and DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE.

Defendant-Appellant.

<u>Patricia A. Carson</u>, Kaye Scholer LLP, of New York, New York, argued for plaintiffs-appellees. With her on the brief were <u>Richard G. Greco</u>; and <u>David O. Bickart</u>, of Washington, DC. Of counsel were <u>Thomas E. Malone</u>, Elan Pharmaceuticals, of South San Francisco, California; and <u>Reem F. Jishi</u>, Wyeth, of Madison, New Jersey.

<u>Christine N. Kohl</u>, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-appellant. On the brief were <u>Tony West</u>, Assistant Attorney General, <u>Channing D. Phillips</u>, Acting United States Attorney, and <u>Scott R. McIntosh</u> and <u>Abby C. Wright</u>, Attorneys. Of counsel on the brief were <u>James A. Toupin</u>, General Counsel, and <u>Raymond T. Chen</u>, Deputy General Counsel and Solicitor, United States Patent and Trademark Office, of Arlington, Virginia.

William G. James, II, Kenyon & Kenyon LLP, of Washington, DC, for amicus curiae Hospira, Inc. With him on the brief was <u>Richard W. Ward</u>.

<u>Jeffrey B. Elikan</u>, Covington & Burling LLP, of Washington, DC, for amicus curiae Pharmaceutical Research and Manufacturers of America, et al. With him on the brief were E. Edward Bruce and James P. Sullivan.

Appealed from: United States District Court for the District of Columbia

Judge James Robertson

United States Court of Appeals for the Federal Circuit

2009-1120

WYETH and ELAN PHARMA INTERNATIONAL LIMITED.

Plaintiffs-Appellees,

٧.

David J. Kappos, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY and DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendant-Appellant.

Appeal from the United States District Court for the District of Columbia in case no. 07-CV-1492, Judge James Robertson.

DECIDED: January 7, 2010

Before RADER, PLAGER, and MOORE, Circuit Judges.

RADER, Circuit Judge.

I.

On summary judgment, the United States District Court for the District of Columbia held that plaintiffs Wyeth and Elan Pharma International Ltd. (collectively, "Wyeth") were entitled to extended patent term adjustments under 35 U.S.C. § 154(b) due to the Patent and Trademark Office's (the "PTO's") delay in prosecuting their patent applications. Because section 154(b) expressly permits this legal relief, this court affirms.

In 1994, the law changed the effective term of a patent from seventeen years commencing from issuance to twenty years from filing. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). With the change came new ways of compensating patentees for PTO-caused delays during prosecution. Under the previous seventeen-year regime, PTO-caused delays could not affect patent terms because the term commenced upon issuance after any delays during patent acquisition. Under the twenty-year term, however, those delays consumed the effective term of a patent.

In 1999, the American Inventors Protection Act amended 35 U.S.C. § 154(b) to address this new problem. The new Act promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO. This promise took the form of three distinct "guarantees" in 35 U.S.C. § 154(b)(1):

(A) Guarantee of prompt Patent and Trademark Office responses.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to [meet deadlines specified in clauses (i)-(iv)]...

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) Guarantee of no more than 3-year application pendency.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States . . .

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) Guarantee or adjustments for delays due to interferences, secrecy orders, and appeals.--Subject to the limitations under paragraph (2) . . . the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

(emphases added). To summarize, paragraph A (the "A guarantee" or "A clause") promises "prompt [PTO] responses" by extending the term of the patent one day for each day the PTO does not meet certain examination deadlines in subdivisions (i)-(iv). Id. § 154(b)(1)(A). One of these deadlines, for instance, requires a first response to a filed application within fourteen months. See id. § 154(b)(1)(A)(i). Paragraph B (the "B guarantee" or "B clause") extends the term of the patent one day for each day issuance is delayed due to the PTO's failure "to issue a patent within 3 years after the actual filing date of the application in the United States." Id. § 154(b)(1)(B). Last, paragraph C allows for adjustments relating to delays resulting from interference proceedings, secrecy orders, and appeals. Id. § 154(b)(1)(C). At issue in this case are the A and B guarantees.

Both the A and B clauses are expressly subject to paragraph 2's "In general" limitation:

In general. To the extent that <u>periods of delay attributable to grounds</u> <u>specified in paragraph (1) overlap</u>, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

<u>Id.</u> § 154(b)(2)(A) (emphasis added). In other words, this limitation restricts the period of adjustment when any of the "periods of delay" "overlap." This case asks this court to interpret and enforce the guarantees in the face of an "overlap" and "periods of delay" under section 154(b)(2)(A).

Section 154(b)(3) of the statute directs the PTO to "prescribe regulations establishing <u>procedures</u> for the application for and determination of patent term adjustments under this subsection." <u>Id.</u> § 154(b)(3) (emphasis added). Under the guise

of that authority, the PTO promulgated 37 C.F.R. § 1.703(f) in 2000: "To the extent that periods of adjustment attributable to the [guarantees] overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed." (emphasis added). Other than adding the term "periods of adjustment," this language repeated the text of section 154(b)(2)(A). The regulations later defined "periods of adjustment" as "the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed" 37 C.F.R. § 1.703(b) (2000). The regulation supplied no explanation about implementation or application of these rules.

In 2004, the PTO amended the regulation to replace "periods of adjustment" with "periods of delay." 69 Fed. Reg. 21706 (2004). The PTO contended that this substitution clarified the regulation:

The language of former § 1.703(f) misled applicants into believing that [periods of A-delay] and [periods of B-delay] were overlapping only if the [period of A-delay] occurred more than three years after the actual filing date of the application. If an application is entitled to a [B-]adjustment . . . the entire period during which the application was pending before the [PTO] . . ., and not just the period beginning three years after the actual filing date of the application; is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A).

<u>Id.</u> (emphasis added). Thus, the "period of delay," according to the PTO's new definition, caused the B guarantee to start with the filing of the application, not three years later. Under that interpretation, "overlap" between A adjustments and B adjustments can arise and begin during the pendency of the patent application. For example, if a patent entitled to twenty days of A adjustments issues twenty days after the three year mark, then it is only entitled to a total of twenty days of adjustment. In

other words, the entire period of A delay "overlaps" with the entire period of B delay.

Using this framework, the PTO uses either the greater of the A delay or B delay to determine the appropriate adjustment but never combines the two.

Wyeth and Elan Pharma are the owners of U.S. Patent Nos. 7,179,892 (the "'892 patent") and 7,189,819 (the "'819 patent")—inventions that treat Alzheimer's disease. During the prosecution of each of their respective applications, the PTO undisputedly caused delays that gave the applicants entitlement to both A and B guarantees.

For the '892 patent, the PTO calculated 610 days of A delay and 345 days of B delay. Of the 610 days of A delay, 51 occurred more than three years after the application was filed. During the prosecution, the applicant caused 148 days of delay. Thus, under section 154(b)(2)(C), any adjustment must be reduced by that amount. See 35 U.S.C. 154(b)(2)(C). Under its greater-of-A-or-B rubric, the PTO calculated the total adjustment at 462 days—i.e., 610 (the greater of A or B) - 148 (applicant delay). According to Wyeth, however, the "period of delay" for purposes of the B clause could not have started until three years after the application's filing date. For that reason, the only possible "overlap" was any A delay occurring after the three-year mark. Because only 51 days of A delay occurred after the three year mark for the '892 patent, the adjustment, according to Wyeth, should have been 756 days—i.e., 610 (A delay) + 345 (B delay) - 51 ("overlap") - 148 (applicant delay).

For the '819 patent, the PTO calculated 336 days of A delay and 827 days of B delay. Of the 336 days of A delay, 106 occurred after the three-year mark. In this case, the applicant caused 335 days of delay. The greater-of-A-or-B rubric yields an adjustment period of 492 days—i.e., 827 (the greater of A or B) - 335 (applicant delay).

Wyeth contends the adjustment period should have been 722 days—i.e., 336 (A delay) + 827 (B delay) - 106 ("overlap") - 335 (applicant delay).

After filing petitions for reconsideration of the adjustments with the PTO, Wyeth filed the instant action in the District Court for the District of Columbia seeking an order directing the PTO to grant an adjustment per Wyeth's interpretation. Both parties filed motions for summary judgment. Citing section 154(b)(3) as evidence of a delegation of authority to draft regulations, the PTO sought <u>Chevron</u> deference for its interpretation. See Chevron U.S.A., Inc. v. Natural Resources Def. Council, Inc., 467 U.S. 837 (1984).

The district court sided with Wyeth, finding first that the PTO "does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency." Wyeth v. Dudas, 580 F. Supp. 2d 138, 141 (D.D.C. 2008) (citing Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996)). The district court further found that even if Chevron was applicable, it would have rejected the PTO's interpretation as contrary to the plain language of the statute. As the district court put it: "The problem with the PTO's interpretation is that it considers the application delayed under [the B guarantee] during the period before it has been delayed." Id. at 142 (emphasis in original).

III.

This court reviews a grant of summary judgment without deference. <u>Johns Hopkins Univ. v. CellPro, Inc.</u>, 152 F.3d 1342, 1353 (Fed. Cir. 1998). Summary judgment is only appropriate if the court determines that there "is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Because both parties in the instant case perceive no genuine

issues of material fact, this court need only decide the question of law decided by the district court. "That question is one of statutory interpretation, one that an appellate court can independently determine without deference to the trial court's interpretation." Glaxo Operations UK Limited v. Quigg, 894 F.2d. 392, 395 (Fed. Cir. 1990) (citing Madison Galleries, Ltd. v. United States, 870 F.2d 627, 629 (Fed. Cir. 1989)).

"As always, the 'starting point in every case involving construction of a statute is the language itself." <u>United States v. Hohri</u>, 482 U.S. 64, 68 (1987) (quoting <u>Kelly v. Robinson</u>, 479 U.S. 36, 43 (1986)). When the terms of a statute are unambiguous, "judicial inquiry is complete, except 'in rare and exceptional circumstances." <u>Rubin v. United States</u>, 449 U.S. 424, 430 (1981) (quoting <u>TVA v. Hill</u>, 437 U.S. 153, 187 n.33 (1978)). "Absent a clearly expressed legislative intention to the contrary, [the statute's plain] language must ordinarily be regarded as conclusive." <u>Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.</u>, 447 U.S. 102, 108 (1980).

This court detects no ambiguity in the terms "periods of delay" and "overlap." Each term has an evident meaning within the context of section 154(b). The limitation in section 154(b) only arises when "periods of delay" resulting from violations of the three guarantees "overlap." 35 U.S.C. § 154(b)(2)(A). Significantly, the A and B guarantees expressly designate when and for what period they each respectively apply. Thus, this court can easily detect any overlap by examining the delay periods covered by the A and B guarantees.

A violation of the A guarantee—delays in meeting examination deadlines—begins with a "failure of the [PTO]" to meet one of the deadlines specified in subparagraphs (i)–(iv). Id. § 154(b)(1)(A). It ends when "the action described . . . is

taken." <u>Id.</u> The "period of delay" for purposes of the A clause therefore runs from the date the PTO misses the specified deadline to the date (past the deadline) of response to the underlying action.

Correspondingly, a violation of the B guarantee—the one at the heart of the issue in this case—begins when the PTO fails "to issue a patent within 3 years after the actual filing date of the application in the United States" <u>Id.</u> § 154(b)(1)(B). It ends when "the patent is issued." <u>Id.</u> The "period of delay" under the express language of the B clause therefore runs from the three-year mark after filing until the application issues.

Reading this framework into section 154(b)'s limitation provision makes it clear that no "overlap" happens unless the violations occur at the same time. Each "period of delay" has its own discrete time span whose boundaries are defined in section 154(b)(1). That is, each has a start and an end. Before the three-year mark, no "overlap" can transpire between the A delay and the B delay because the B delay has yet to begin or take any effect. If an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(b)(2).

Under the PTO's strained interpretation, B delay can occur <u>anytime</u> after the application is filed. To the contrary, the language of section 154(b) does not even permit B delay to start running until three years <u>after</u> the application is filed. The PTO's position cannot be reconciled with the language of the statute. Thus, returning to the district court's decision, this time with affirming approval: "The problem with the PTO's interpretation is that it considers the application <u>delayed</u> under [the B guarantee] during the period <u>before it has delayed</u>." <u>Wyeth</u>, 580 F. Supp. 2d at 142 (emphasis in original).

The PTO defends its interpretation by arguing that A delays during the first three years of prosecution ultimately lead to B delays after the three-year mark from filing. Put differently, it would be double counting if A and B delays were both used to adjust because A delays "cause" B delays. In that vein, the PTO highlights various scenarios where a hypothetical patentee appears to receive some type of windfall adjustment under the statute despite being in a similar position as other applicants who receive no similar adjustment. Indeed, the statute requires as much. Nonetheless, this court perceives potential perverse results as well under the PTO's suggested interpretations. Under certain scenarios, both the PTO's interpretation and the statute itself result in some imbalanced treatment of similarly-situated patentees.

For example, the language of section 154(b) presents a slight imbalance in the following hypothetical: suppose Applicant 1 receives a patent 3 years and 30 days after filing an application. In prosecuting the application, Applicant 1 incurred 30 days of A delay before the three-year mark. In the same hypothetical situation, suppose Applicant 2 also receives a patent 3 years and 30 days after filing an application but incurred no A delay during prosecution. Notably, both patents issued the same amount of time from filing—3 years and 30 days. Nonetheless, Applicant 1 would receive a 60 day adjustment whereas Applicant 2 would only receive a 30 day adjustment meaning Applicant 1's effective term would be 30 days longer than Applicant 2.

By the same token, under the PTO's counter-statutory interpretation, suppose Applicant 1 incurs 400 days of A delay before the three-year mark with the application issuing exactly three years after filing. Suppose Applicant 2 also incurs 400 days of A delay before the three-year mark, but in addition incurs a one-year delay by the PTO

after the three-year mark. Despite the fact each applicant incurred the same A delay, under the PTO's interpretation, Applicant 1's effective term would be a full year greater than Applicant 2's effective term. Simply put, the additional B delay incurred by Applicant 2 produces a shorter effective term.

Regardless of the potential of the statute to produce slightly different consequences for applicants in similar situations, this court does not take upon itself the role of correcting all statutory inequities, even if it could. In the end, the law has put a policy in effect that this court must enforce, not criticize or correct. See Harbison v. Bell, 129 S. Ct. 1481, 1493-94 (2009) (Thomas, J., concurring) (quoting Eldred v. Ashcroft, 537 U.S. 186, 222 (2003) ("Even if the proper interpretation of a statute upholds a 'very bad policy,' it 'is not within our province to second-guess' the 'wisdom of Congress' action' by picking and choosing our preferred interpretation from among a range of potentially plausible, but likely inaccurate, interpretations of a statute.")).

The PTO also passingly refers to the second clause of section 154(b)(2)(A) for support: "the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). While the PTO's argument on this point is unclear, that language does not provide any support for its interpretation. Significantly, the second clause of section 154(b)(2)(A) only takes effect upon satisfaction of the first clause. See id. § 154(b)(2)(A) ("To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap") (emphasis added). Viewed in this light, a "delay" must refer consistently to the violation of either the A or B guarantees. "[T]he actual number

of days the issuance of the patent was delayed" therefore refers to each day covered by a "period of delay" in the first clause with no such day counted twice.

This court has also examined the legislative history of the 1999 Act but finds nothing to rescue the PTO's cause. In the first place, only a "most extraordinary showing of contrary intentions" by Congress justifies a departure from the plain language of a statute. Garcia v. United States, 469 U.S. 70, 75 (1984). Far from intentions contrary to the meaning of section 154(b), the legislative history generally supports the interpretation required by the statutory language itself. The AIPA's section-by-section analysis states:

Accordingly, subtitle D removes the 10-year caps from the existing provisions, adds a new provision to compensate applicants fully for USPTO-caused administrative delays, and, for good measure, includes a new provision guaranteeing diligent applicants at least a 17-year term by extending the term of any patent not granted within three years of filing. Thus, no patent applicant diligently seeking to obtain a patent will receive a term of less than the 17 years as provided under the pre-GATT standard; in fact, most will receive considerably more.

H.R. Rep. No. 106-464, at 125 (1994) (emphases added). From this, it is apparent that the statutory language should provide a <u>minimum</u> seventeen-year term for most patents. The outcome suggested by the language itself effectuates this goal by ensuring such a minimum term unless the applicant caused delays.

The PTO urges this court to read that passage in view of the 25-month average patent pendency at that time—that is, most patents received more than a seventeen-year term because of the shorter prosecution periods. Even taking that context into account, this court notes that the PTO's interpretation effectively creates a seventeen-year term <u>cap</u> where B delays are greater than A delays. In other words, any A delay before the three-year mark causes PTO delays in issuance beyond the three-year

mark—thereby violating the B guarantee. Together, these effects, under the PTO's desire to aggregate A and B delays, reduce the effective term of the patent towards seventeen years. The passage from the House report does not expressly preclude that type of effective cap, but the context suggests a very different goal of supplying adequate protection that will often be "considerably more" than the PTO's effective cap. In any event, the House report does not produce any "extraordinary showing of contrary intentions." Moreover, if the Act intended to create a seventeen-year cap, it could have easily done so with just a few words.

The PTO next highlights the belated addition of the B guarantee into section 154(b) for support. Before enactment of AIPA, section 154(b) only provided extensions for the category that now fall under C adjustments. See 35 U.S.C. § 154(b)(1)-(2) (1996). The earlier versions of AIPA added only A delays. See S. 507, 105th Cong., 143 Cong. Rec. S2678, S2696-97 (Mar. 20, 1997). Not long afterwards, B adjustments appeared in drafts of section 154(b). See H.R. 400, 105th Cong., 143 Cong. Rec. H1629, H1651 (April 17, 1997). According to the PTO, this legislative history suggests that Congress did not intend to give patentees already eligible for A adjustments additional compensation where the A delay occurred during the first three years of prosecution. Even if these ambiguous timing observations suggested some kind of substantive difference in the meaning of section 154(b), they would be wholly irrelevant to interpretation of the law itself. Such opaque timing observations hardly amount to a "most extraordinary showing of contrary intentions," especially when the language of the statute trumpets its meaning by itself. See Harbison, 129 S. Ct. at 1494 (Thomas, J., concurring) ("And Congress' silence certainly does not empower us to go even farther

and incorporate such an assumption into the text of these provisions."). In sum, legislative history—always a very dull instrument for extracting the essence of statutory meaning—provides no reason to depart from the language of section 154(b).

Last, the PTO contends that its interpretation is entitled to deference under either Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) or Skidmore v. Swift & Co., 323 U.S. 134 (1944). Because the language of the statute itself controls this case and sets an unambiguous rule for overlapping extensions, this court detects no reason to afford special deference to the PTO's interpretation. See Smith v. City of Jackson, Miss., 544 U.S. 228, 267 (2005) (quoting Pub. Employees Ret. Sys. of Ohio v. Betts, 492 U.S. 158, 171 (1989)) ("Of course, it is elementary that 'no deference is due to agency interpretations at odds with the plain language of the statute itself.").

IV.

This court therefore affirms the judgment of the district court. Section 154(b)'s language is clear, unambiguous, and intolerant of the PTO's suggested interpretation. For that reason, this court accords no deference to the PTO's greater-of-A-or-B rubric.

<u>AFFIRMED</u>

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